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BARRIER MATERIAL

The present invention relates to the new use of a known material in the manufacture of a barrier material to ethylene oxide gas. The invention further relates to an article which is required to be impermeable to ethylene oxide gas, a process for making such an article and a package which contains such an article. The invention is particularly, although not exclusively, concerned with a fluid container which contains sterile wetting fluid for wetting of a urinary catheter having a surface coating which exhibits a reduced friction when wetted prior to insertion of the catheter into the urethra of a patient.

The use of ethylene oxide gas as a sterilising medium for medical articles is well known. A case in point is the use of ethylene oxide for sterilising catheters such as urinary catheters. This is typically achieved after the catheter has been housed in a container, for instance a transparent urine collection bag in the case of a urinary catheter, the bag being adapted for the urinary catheter to project therethrough into the urethra of a patient with the urine transported out of the bladder through the catheter being collected in the urine collection bag. The urine collection bag presents a pathway for the access of ethylene oxide thereinto for sterilising the catheter and the inner surface of the bag. This pathway is typically an inlet to the bag through which the catheter is placed into the bag.

Many urinary catheters are provided with a surface coating which exhibits a reduced friction when wetted, thus facilitating insertion of the catheter into the urethra. Non-limiting examples of such coatings are given in Applicant's European patent Nos. 0093093 and 0217771. It is therefore useful to include in the urine collection bag a fluid container which contains a wetting fluid for wetting of the catheter prior to use thereof. A typical wetting fluid is water or saline. These fluids can react with ethylene oxide gas to form ethylene glycol which is not desirable. Furthermore, unreacted ethylene oxide may be retained in the fluid which is also undesirable. It is thus preferable that the fluid container contain a pre-sterilised wetting fluid such as sterile water or saline and that the container be constructed from a barrier material to ethylene oxide gas as well as to the fluid contained in the container. To date, aluminium foil, poly(vinylidene chloride) and metallised films such as

metallised poly(ethylene terephthalate) have been proposed for the manufacture of the fluid container.

A problem with these materials is that they are opaque. The catheter packages are usually for self-administration of the catheter by a patient and the confidence of these patients in using the package would be increased if the fluid container were transparent so that they could see the contents thereof.

It has surprisingly been found by the Applicants that a transparent ethylene oxide impermeable fluid container can be manufactured by using a silicon oxide, for instance a silicon dioxide.

According to a first aspect of the present invention there is thus provided the use of a silicon oxide in the manufacture of a barrier material to ethylene oxide gas.

In an embodiment of the invention the barrier material includes a polyester, polyethylene terephthalate, nylon or polypropylene as a support for the silicon oxide.

In an embodiment of the invention the barrier material is a laminate comprising an outer layer, an inner layer and one or more intermediate layers in-between the outer and inner layers with the silicon oxide being contained in one of the layers of the laminate.

In an embodiment of the invention the silicon oxide and support material therefor define one of the layers of the laminate.

In an embodiment of the invention the inner layer contains polyethylene or polypropylene, the outer layer contains a polyester or polypropylene and the, or one or more of the, intermediate layers in-between the inner and outer layers contains the silicon oxide.

In an embodiment of the invention the outer layer contains the silicon oxide and a polyester or polypropylene.

In an embodiment of the invention the inner layer contains the silicon oxide and polypropylene.

In an embodiment of the invention the barrier material presents a boundary wall of a container which is to be exposed to ethylene oxide gas and further which contains a substance which is required to be kept free from the ethylene oxide gas.

According to second aspect of the invention there is provided an article which is required to be impermeable to ethylene oxide gas, the article being constructed from a construction which comprises a silicon oxide.

According to a third aspect of the invention there is provided a process for the manufacture of an article which is required to be impermeable to ethylene oxide gas, the process comprising the step of forming the article from a construction which comprises a silicon oxide.

In an embodiment of the invention according to the second and third aspects the article is a container which is to be exposed to ethylene oxide gas and further which contains a substance which is required to be kept free from the ethylene oxide gas with the silicon oxide being contained in the boundary wall of the container. The boundary wall of the container can be constructed from the barrier material in accordance with the first aspect of the invention, e.g. a laminate which contains a silicon oxide in one or more of the layers thereof.

According to a fourth aspect of the invention there is provided a package which is to be exposed to ethylene oxide gas, the package comprising a container which is constructed so as to present a pathway for access of ethylene oxide gas thereinto, a first article housed in

the container which is required to be sterilised by the ethylene oxide gas and a second article housed in the container which is required to be impermeable to ethylene oxide gas and which is formed from a construction which comprises a silicon oxide. The construction of the second article can be in the form of the barrier material in accordance with the first aspect of the invention.

In an embodiment of the invention according to the fourth aspect hereinafter to be described the package is a catheter package with the container taking the form of a urine collection bag, the first article taking the form of a urinary catheter having a surface coating which has a reduced friction when wetted and the second article taking the form of a fluid container which contains a sterile fluid for wetting of the catheter prior to insertion thereof into the urethra of a patient.

By way of example embodiments of the invention will now be described with reference to the accompanying Figures of drawings in which:-

Fig. 1 shows a catheter package in accordance with the invention comprising a urine collection bag and a wetting fluid container integrated therewith;

Fig. 2 shows another catheter package in accordance with the invention comprising a urine collection bag and an unopened wetting fluid sachet in accordance with the invention integrated therewith in an operational position in the inlet of the urine collection bag;

Fig. 3 is an exploded view of the unopened sachet of the catheter package shown in Fig. 2 in the operational position in the inlet of the urine collection bag;

Fig. 4 is a front view of the unopened sachet of the catheter package shown in Fig. 2 in an extended configuration prior to insertion thereof into the inlet of the urine collection bag to the operational position;

Fig. 5 is a side view of the unopened sachet shown in Fig. 4;

Fig. 6 is a perspective view of the unopened sachet of the catheter package shown in Fig. 2 in a retracted configuration ready for insertion into the inlet of the urine collection bag to the operational position;

Fig. 7 corresponds to Fig. 2 but with the wetting fluid sachet having been opened; and

Fig. 8 corresponds to Fig. 3 but with the wetting fluid sachet having been opened.

Referring first to Fig. 1, there is shown a catheter package 10 in accordance with the invention comprising a urine collection bag 1 of a transparent flexible plastics material. The bag 1 presents at the forward end thereof an elongate pocket 2 of depth sufficient to receive at least the insertable length of a hydrophilic urinary catheter 3. The urine collection bag 1 further defines to the rear of the pocket 2 a urine collection chamber 12 which is in fluid communication with the pocket 2. Further rearwardly is an inlet 14 to the urine collection bag 1 through which the hydrophilic urinary catheter 3 is able to be positioned into the bag 1.

As can be seen, the catheter 3 comprises a flared rearward portion 16 and an elongate shaft 18 which extends forwardly from the rearward portion 16 and terminates in a rounded tip 4 at the forward end thereof. The catheter 3 is provided with a lumen (not shown) which extends from an open end in the rearward portion 16 to a drainage aperture 5 in the tip 4.

A container in the form of a sachet 6 is secured to the inner surface of the urine bag 1. The sachet 6 contains sterile water or saline or other fluid suitable for wetting the hydrophilic urinary catheter 3 and is pierceable or otherwise openable, for example by applying a hand pressure, so as to release substantially all of the water or saline contained therein into the pocket 2 immediately prior to use of the catheter 3.

The urine collection bag 1 with integrated sachet 6 and catheter 3 needs to be sterilised using ethylene oxide prior to use. Since the sachet 6 contains sterile water or saline there is no need for sterilising the contents of the sachet 6 though. Accordingly, the material of the sachet 6 needs to be impermeable to both ethylene oxide and water and, for increased confidence of a self-administrating patient, transparent. To these ends, the sachet 6 is constructed from a laminate comprising an outer facing layer of polypropylene, an inner layer of polyethylene and an intermediate layer made from the silicon oxide containing material Techbarrier-S marketed by Mitsubishi. Gas chromatography tests show that such a construction is impermeable to ethylene oxide gas.

The outer layer of the sachet construction could instead be formed from a polyester, the inner layer from polypropylene and the intermediate layer from silicon oxide with a polyester, polyethylene terephthalate, nylon or polypropylene as a support therefor.

The volume of the sachet 6 is sufficient to release such an amount of water or saline into the pocket 2 to enable wetting of the insertable length of the catheter 3 immediately prior to use. By "insertable length" is meant at least that length of the elongate shaft 18 which is coated with a hydrophilic material, for example PVP, and inserted into the urethra of the patient. Typically, this will be 80-140 mm for a female patient and 200-350 mm for a male patient.

The holding time of the catheter 3 in the pocket 2 may vary within a broad range but will typically amount to at least 30 seconds.

The location of the sachet 6 inside the bag 1 is not critical as long as the sachet 6 releases its contents into the pocket 2. It is preferred, though, that the sachet 6 be disposed as close to the open end of the pocket 2 as possible. In this embodiment the sachet 6 is permanently fixed in position in the urine collection bag 1, for example by adhesion to the bag 1. It will be appreciated, however, that the sachet 6 could in fact be freely movable in the bag 1.

In use, the inlet 14 is then sealed, for example by tying a knot in the material defining the inlet 14 or by clamping the inlet 14 with a clamp. The sachet 6 is then opened, for example by applying a pressure thereto through the material of the bag 1, to release the wetting fluid into the pocket 2 and the sterilised catheter 3 then left to soak for a predetermined duration in the wetting fluid to wet the hydrophilic outer surface thereof.

Alternately, the bag 1 may be provided with a closed end in place of the inlet with the catheter 3 pre-packaged inside the bag 1. An inlet 14 is preferred, though, as this provides an easy pathway for access of the ethylene oxide to the inside of the bag 1.

After wetting of the catheter 3 for the predetermined duration, the bag 1 is turned upside down and the forwardmost portion of the pocket 2 torn off. The elongate shaft 18 of the catheter 3 is then manoeuvred through the opening in the forward end of the pocket 2 and into the urethra of the patient until the flared rearward portion 16 forms a mechanical seal connection with the opening. There is therefore no need to directly handle the catheter 3 for insertion thereof into the urethra which is to advantage as the outer surface of the catheter 3 will be slippery due to the wetting procedure and therefore difficult to grip and furthermore because the possibility of contamination of the catheter 3 at this stage is avoided.

Urine in the bladder of the patient is transported rearwardly through the lumen of the catheter 3 into the urine collection chamber 12. The catheter 3 is manoeuvred back inside the bounds of the bag 1 and the open end of the pocket 2 closed off for example by tying a knot with the material defining the pocket 2 or clamping the pocket 2 with a clamp. An opening can then be made in the urine collection chamber 12 for the collected urine to be poured away after which the bag 1 can be disposed of.

Turning now to Figs 2 and 3 of the drawings, there is shown an alternative catheter package 110 in accordance with the present invention. The catheter package 110 comprises a urine collection bag 101 of a flexible transparent plastics material which corresponds to the urine collection bag 1 of the catheter package 10 hereinbefore described with reference to Fig. 1

of the drawings. That is to say, the urine collection bag 101 has a downwardly extending elongate pocket 102 at the forward end, a urine collection chamber 112 rearwardly of and in fluid communication with the elongate pocket 102 and an inlet 114 to the bag 101 spaced further rearwardly.

Again as in the catheter package 10 hereinbefore described with reference to Fig. 1, a hydrophilic urinary catheter 103 having a flared rearward portion 116, an elongate shaft 118 projecting forwardly from the rearward portion 116 and an open-ended lumen (not shown) which extends from the rear end of the rearward portion 116 to a drainage aperture 105 in the rounded tip 104 at the forward end of the catheter 103 is positioned into the urine collection bag 101 through the inlet 114 such that preferably at least the insertable length of the catheter 103 is received in the pocket 102.

As can be seen more particularly by reference to Fig. 3, a sterile wetting fluid containing sachet 106 is held in the inlet 114 in an operational position by a friction fit. The sachet 106 has a forward portion 120 which in the operational position of the sachet 106 projects forwardly into the inlet 114 and a rearward portion 122 which in the operational position projects rearwardly out of the inlet 114.

The sachet 106 is made from the same construction as the sachet 6 hereinabove described with reference to Fig. 1. The fit of the sachet 106 in the inlet 114 is not so tight as to prevent ethylene oxide from entering and exiting the inside of the bag 101 and sterilising the inner surface of the bag 101 and outer surfaces of the sachet 106 and catheter 103. The sterile wetting fluid is retained in the sachet 106 by peripheral sealing of the sachet 106 as shown.

Referring now to Figs 4 and 5, the forward portion 120 of the sachet 106 presents a forward edge 124. Extending rearwardly from the forward edge 124 is a tear line 126. Projecting forwardly from the forward edge 124 of the sachet 106 to one side of the tear line 126 is a first tab 128. On the other side of the tear line 126 there is provided an

elongate second tab 130 shown here in an extended position in which the second tab 130 projects forwardly from the forward edge 124.

As shown in Fig. 6, the elongate second tab 130 is movable about the forward edge 124 back on its self from the extended position shown in Figs 4 and 5 to a retracted position in which the second tab 130 extends rearwardly from the forward edge 124. When the second tab 130 is in the retracted position the sachet 106 is inserted into the inlet 114 to the operational position shown in Figs 2 and 3.

Returning now to Figs 2 and 3, it can be seen that the dimensions of the second tab 130 are such that when the sachet 106 is in the operational position a pulling portion 132 of the second tab 130 projects rearwardly from the inlet 114 of the urine collection bag 101 and forms a part of the rearward portion 122 of the sachet 106.

In Figs 7 and 8 there is shown the operation of the sachet 106 to release the contents of the sachet 106 into the pocket 102 to wet the hydrophilic outer coating of the catheter 103. The user grips the first tab 128 through the flexible transparent plastics material of the bag 101 and then pulls rearwardly on the pulling portion 132 of the second tab 130 which projects from the inlet 114 to cause the tear line 126 to be torn and the wetting fluid to be released into the pocket 102 to wet the catheter 103. Preferably, the sachet 106 contains sufficient wetting fluid for the pocket 102 to be filled to a level which results in the insertable length of the catheter 103 being wetted .

After release of the wetting fluid into the pocket 102 the sachet 106 is removed from the bag 101 and disposed of. The bag 101 and catheter 103 are then utilised in the manner hereinabove described for the catheter package 10 shown in Fig. 1.

If need be, the bag 101 can be a closed bag with the sachet 106 and catheter 103 pre-packaged within the bag 101. In this instance, the construction of the bag 101 is such that the bag is permeable to ethylene oxide gas and that the sachet 106 can be opened in the aforementioned manner through the material of the bag 101.

The catheter package 110 described hereinabove with reference to Figs 2 to 8 has the advantage of *inter alia* having a sachet 106 which can better withstand the cyclical pressures which are typically exerted on a catheter package when packaged and subjected to the sterilising process as a consequence of the sachet 106 not having to be opened through application of a direct pressure thereto through the material of the bag 101 in which case a significantly weakened sachet edge would be required as a high pressure could not be applied through the bag 101 without damaging the bag 101.

Claims:

1. Use of a silicon oxide in the manufacture of a barrier material to ethylene oxide gas.

2. Use according to claim 1, characterised in that the barrier material includes a polyester, polyethylene terephthalate, nylon or polypropylene as a support for the silicon oxide.

3. Use according to claim 1 or 2, characterised in that the barrier material is a laminate comprising an outer layer, an inner layer and one or more intermediate layers in-between the outer and inner layers and that the silicon oxide is contained in one of the layers of the laminate.

4. Use according to claim 3 when appendent on claim 2, characterised in that the silicon oxide and support material therefor define one of the layers of the laminate.

5. Use according to claim 3 or 4, characterised in that the inner layer contains polyethylene or polypropylene, the outer layer contains a polyester or polypropylene and the, or one or more of the, intermediate layers in-between the inner and outer layers contains the silicon oxide.

6. Use according to claim 3 or 4, characterised in that the outer layer contains the silicon oxide and a polyester or polypropylene.

7. Use according to claim 3 or 4, characterised in that the inner layer contains the silicon oxide and polypropylene.

8. Use according to any one of the preceding claims, characterised in that the barrier material presents a boundary wall of a container which is to be exposed to ethylene oxide gas and further which contains a substance which is required to be kept free from the ethylene oxide gas.

9. An article which is required to be impermeable to ethylene oxide gas characterised in that the article is constructed from a construction which comprises a silicon oxide.

10. An article according to claim 9, characterised in that the article is a container which is to be exposed to ethylene oxide gas and further which contains a substance which is required to be kept free from the ethylene oxide gas and that the silicon oxide is contained in the boundary wall of the container.

11. A process for the manufacture of an article which is required to be impermeable to ethylene oxide gas characterised by the step of forming the article from a construction which comprises a silicon oxide.

12. A process according to claim 11, characterised in that the article is a container which is to be exposed to ethylene oxide gas and further which contains a substance which is required to be kept free from the ethylene oxide gas and that the silicon oxide is contained in the boundary wall of the container.

13. A package which is to be exposed to ethylene oxide gas, the package comprising a container which is constructed so as to present a pathway for access of ethylene oxide gas thereinto, a first article housed in the container which is required to be sterilised by the ethylene oxide gas and a second article housed in the container which is required to be impermeable to ethylene oxide gas characterised in that the second article is formed from a construction which comprises a silicon oxide.

14. A package according to claim 13, characterised in that the package is a catheter package with the container taking the form of a urine collection bag, the first article taking the form of a urinary catheter having a surface coating which has a reduced friction when wetted and the second article taking the form of a fluid container which contains a sterile fluid for wetting of the catheter prior to insertion thereof into the urethra of a patient.

ABSTRACT

Barrier Material

Use of a silicon oxide in the manufacture of a barrier material to ethylene oxide gas, for instance for forming a container (6) which is to be exposed to ethylene oxide gas and further which contains a substance which is required to be kept free from the ethylene oxide gas.

(Fig. 1)

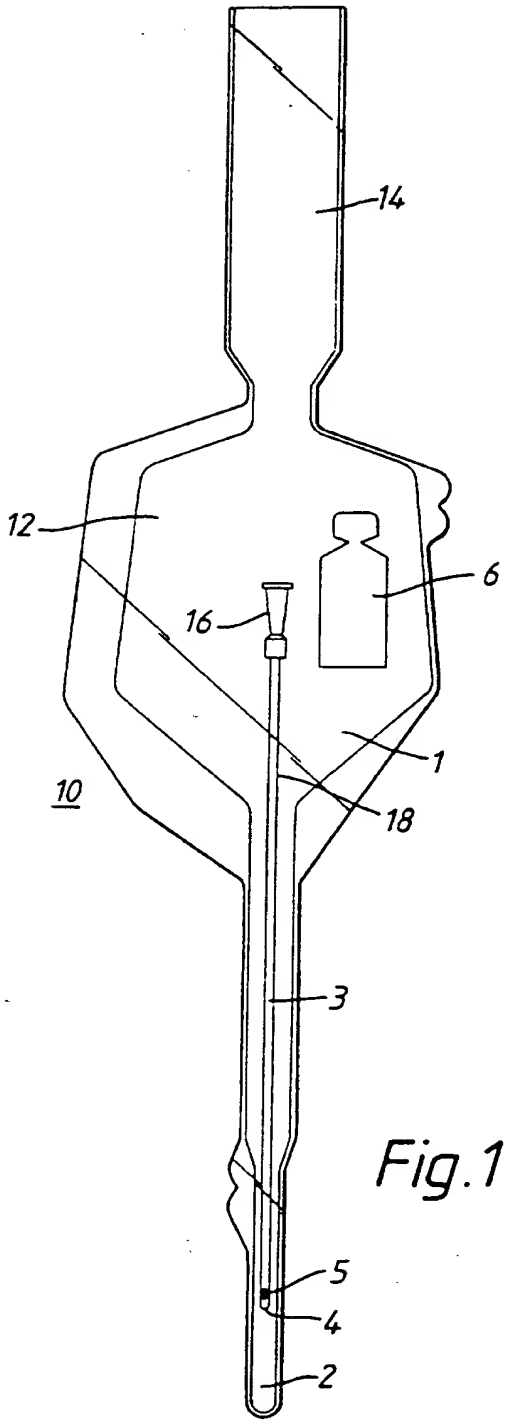
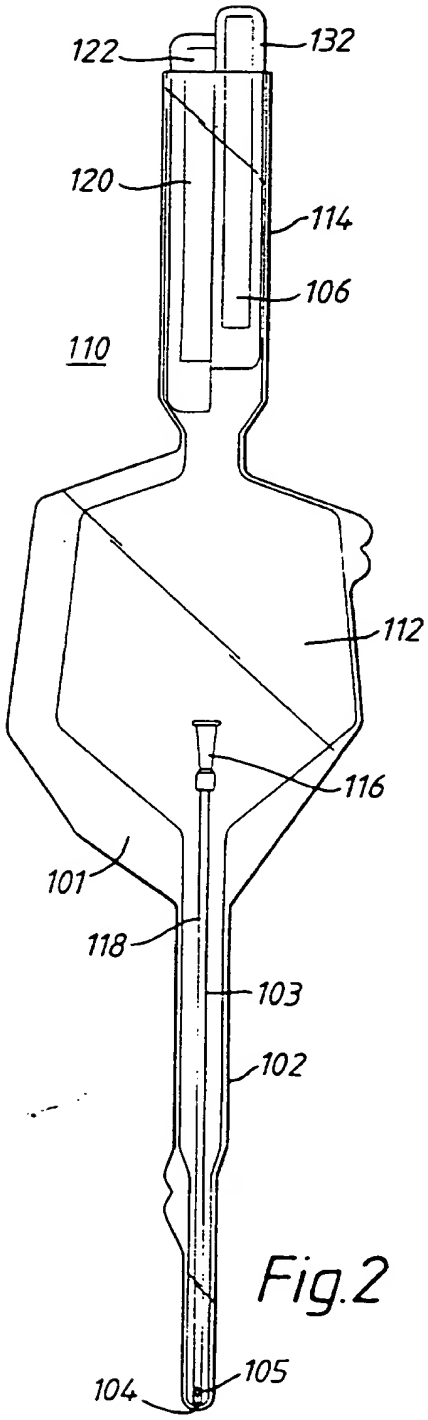


Fig.1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132
120
114
106
110
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116
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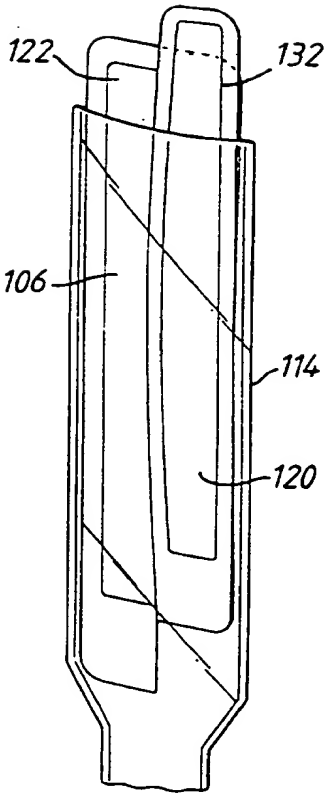
104
105

Fig.2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132
106
114
120

Fig.3

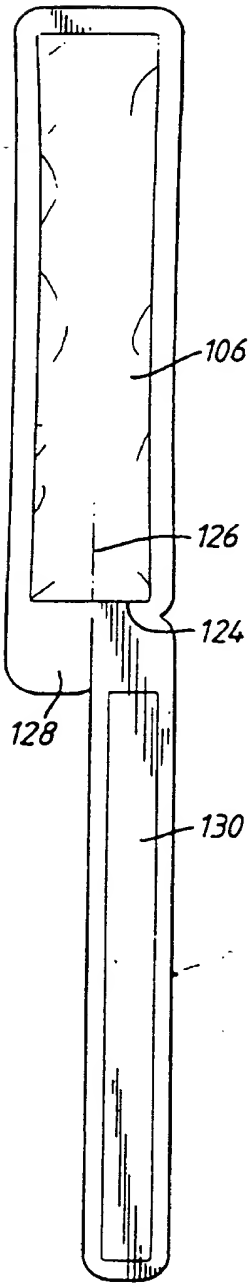

Fig.4

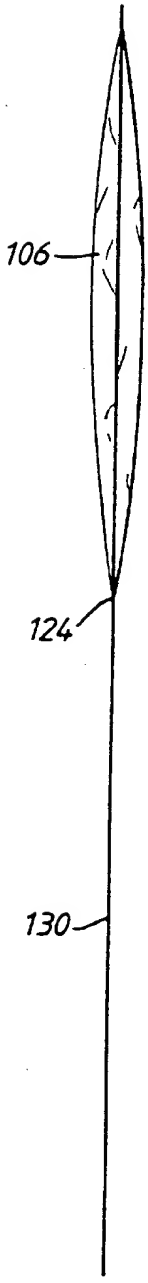

Fig.5

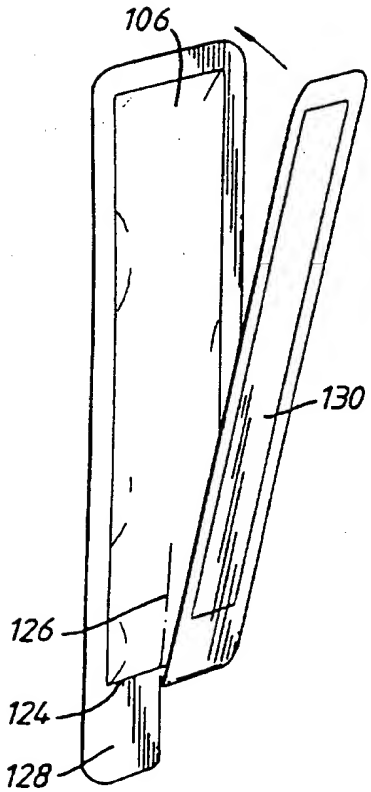

Fig.6

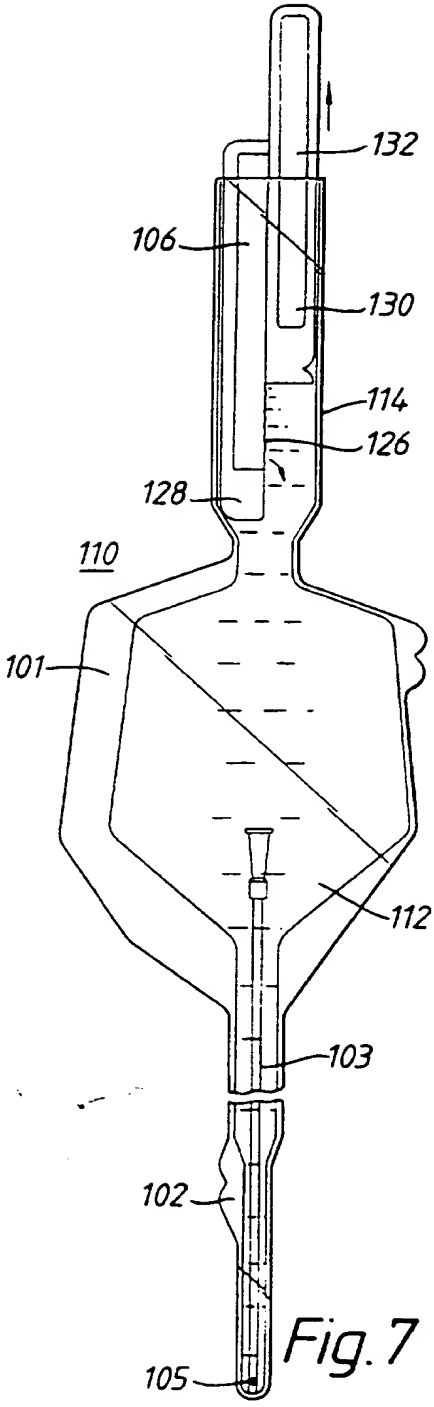

Fig. 7

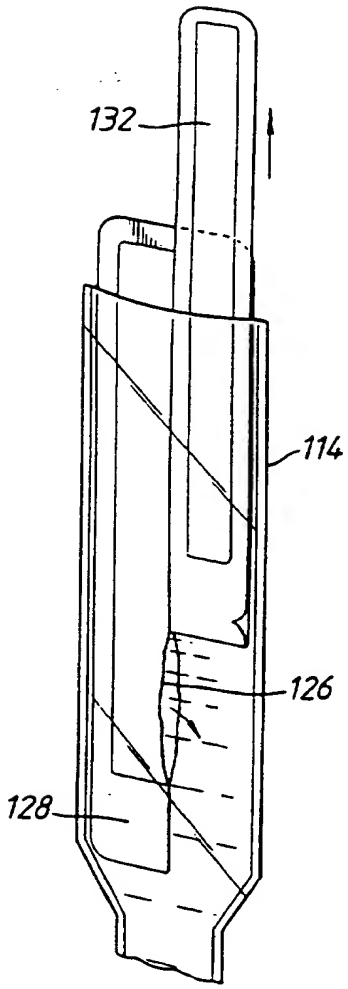

Fig. 8